

**EPIPEN- epinephrine injection**  
**EPIPEN JR- epinephrine injection**  
**Dey Pharma L.P.**

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**EPIPEN<sup>®</sup>**

**(epinephrine) Auto-Injector 0.3 mg**

**EpiPen<sup>®</sup> = one dose of 0.30 mg epinephrine (USP, 1:1000, 0.3 mL)**

**EPIPEN JR<sup>®</sup>**

**(epinephrine) Auto-Injector 0.15 mg**

**EpiPen Jr<sup>®</sup> = one dose of 0.15 mg epinephrine (USP, 1:2000, 0.3 mL)**

**PRESCRIBING INFORMATION**

**DESCRIPTION**

Each EpiPen<sup>®</sup> Auto-Injector delivers **a single dose** of 0.3 mg epinephrine injection, USP, 1:1000 (0.3 mL) in a sterile solution.

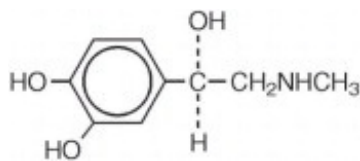
Each EpiPen Jr<sup>®</sup> Auto-Injector delivers **a single dose** of 0.15 mg epinephrine injection, USP, 1:2000 (0.3 mL) in a sterile solution.

The EpiPen Auto-Injector and EpiPen Jr Auto-Injector (henceforth referred to as EpiPen and EpiPen Jr Auto-Injector) each contain 2 mL epinephrine solution. Approximately 1.7 mL remains in the auto-injector after activation and cannot be used.

Each 0.3 mL in the EpiPen Auto-Injector contains 0.3 mg epinephrine, 1.8 mg sodium chloride, 0.5 mg sodium metabisulfite, hydrochloric acid to adjust pH, and Water for Injection. The pH range is 2.2-5.0.

Each 0.3 mL in the EpiPen Jr Auto-Injector contains 0.15 mg epinephrine, 1.8 mg sodium chloride, 0.5 mg sodium metabisulfite, hydrochloric acid to adjust pH, and Water for Injection. The pH range is 2.2-5.0.

Epinephrine is a sympathomimetic catecholamine. Chemically, epinephrine is B-(3, 4-dihydroxyphenyl)-a-methyl-aminoethanol, with the following structure:



Epinephrine solution deteriorates rapidly on exposure to air or light, turning pink from oxidation to adrenochrome and brown from the formation of melanin. Replace EpiPen and EpiPen Jr Auto-Injectors if the epinephrine solution appears discolored.

EpiPen and EpiPen Jr Auto-Injectors do not contain latex.

**CLINICAL PHARMACOLOGY**

Epinephrine is the drug of choice for the emergency treatment of severe allergic reactions (Type I) to insect stings or bites, foods, drugs, and other allergens. It can also be used in the treatment of anaphylaxis of unknown cause (idiopathic anaphylaxis) or exercise-induced anaphylaxis. When given intramuscularly or subcutaneously it has a rapid onset and short duration of action. Epinephrine acts on both alpha and beta adrenergic receptors. Through its action on alpha adrenergic receptors, epinephrine lessens the vasodilation and increased vascular permeability that occurs during anaphylaxis, which can

lead to loss of intravascular fluid volume and hypotension. Through its action on beta-adrenergic receptors, epinephrine causes bronchial smooth muscle relaxation that helps alleviate bronchospasm, wheezing and dyspnea that may occur during anaphylaxis. Epinephrine also alleviates pruritus, urticaria, and angioedema and may be effective in relieving gastrointestinal and genitourinary symptoms associated with anaphylaxis because of its relaxer effects on the smooth muscle of the stomach, intestine, uterus, and urinary bladder.

## INDICATIONS AND USAGE

EpiPen and EpiPen Jr Auto-Injectors are indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitos), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis. EpiPen and EpiPen Jr Auto-Injectors are intended for immediate administration in patients, who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions. Selection of the appropriate dosage strength is determined according to patient body weight (see **DOSAGE AND ADMINISTRATION** section).

Such reactions may occur within minutes after exposure and consist of flushing, apprehension, syncope, tachycardia, thready or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus, rashes, urticaria or angioedema.

EpiPen and EpiPen Jr Auto-Injectors are intended for immediate self-administration as emergency supportive therapy only and are not a substitute for immediate medical care.

## CONTRAINDICATIONS

There are no absolute contraindications to the use of epinephrine in a life-threatening situation.

## WARNINGS

EpiPen and EpiPen Jr Auto-Injectors should **only** be injected into the anterolateral aspect of the thigh. **DO NOT INJECT INTO BUTTOCK.** Injection into the buttock may not provide effective treatment of anaphylaxis. Advise the patient to go immediately to the nearest emergency room for further treatment of anaphylaxis.

Since epinephrine is a strong vasoconstrictor, accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area. Treatment should be directed at vasodilation in addition to further treatment of anaphylaxis (see **ADVERSE REACTIONS**). Advise the patient to go immediately to the nearest emergency room and to inform the healthcare provider in the emergency room of the location of the accidental injection.

**DO NOT INJECT INTRAVENOUSLY.** Large doses or accidental intravenous injection of epinephrine may result in cerebral hemorrhage due to sharp rise in blood pressure. Rapidly acting vasodilators can counteract the marked pressor effects of epinephrine if there is such inadvertent administration.

Epinephrine is the preferred treatment for serious allergic reactions or other emergency situations even though this product contains sodium metabisulfite, a sulfite that may, in other products, cause allergic-type reactions including anaphylactic symptoms or life-threatening or less severe asthmatic episodes in certain susceptible persons. The alternatives to using epinephrine in a life-threatening situation may not be satisfactory. The presence of a sulfite in this product should not deter administration of the drug for treatment of serious allergic or other emergency situations even if the patient is sulfite-sensitive.

Epinephrine should be administered with caution in patients who have heart disease, including patients

with cardiac arrhythmias, coronary artery or organic heart disease, or hypertension. In such patients, or in patients who are on drugs that may sensitize the heart to arrhythmias, e.g., digitalis, diuretics, or anti-arrhythmics, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias. It should be recognized that the presence of these conditions is not a contraindication to epinephrine administration in an acute, life-threatening situation.

Epinephrine is light sensitive and should be stored in the carrier tube provided. Store at 20° to 25°C (68° to 77°F); excursions permitted to 15°C-30°C (59°F-86°F) (See USP Controlled Room Temperature). Do not refrigerate. Protect from light. Before using, check to make sure the solution in the auto-injector is not discolored. Replace the auto-injector if the solution is discolored or contains a precipitate.

## **PRECAUTIONS**

### **(1) General**

EpiPen and EpiPen Jr Auto-Injectors are not intended as a substitute for immediate medical care. In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care. More than two sequential doses of epinephrine should only be administered under direct medical supervision.

Epinephrine is essential for the treatment of anaphylaxis. Patients with a history of severe allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs, and other allergens as well as idiopathic and exercise-induced anaphylaxis should be carefully instructed about the circumstances under which epinephrine should be used. It must be clearly determined that the patient is at risk of future anaphylaxis, since the following risks may be associated with epinephrine administration (see **DOSAGE and ADMINISTRATION**).

Epinephrine should be used with caution in patients who have cardiac arrhythmias, coronary artery or organic heart disease, hypertension, or in patients who are on drugs that may sensitize the heart to arrhythmias, e.g., digitalis, diuretics, quinidine, or other anti-arrhythmics. In such patients, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias.

The effects of epinephrine may be potentiated by tricyclic antidepressants and monoamine oxidase inhibitors.

Some patients may be at greater risk of developing adverse reactions after epinephrine administration. These include: hyperthyroid individuals, individuals with cardiovascular disease, hypertension, or diabetes, elderly individuals, pregnant women, pediatric patients under 30 kg (66 lbs.) body weight using EpiPen Auto-Injector, and pediatric patients under 15 kg (33 lbs.) body weight using EpiPen Jr Auto-Injector.

Despite these concerns, epinephrine is essential for the treatment of anaphylaxis. Therefore, patients with these conditions, and/or any other person who might be in a position to administer EpiPen or EpiPen Jr Auto-Injector to a patient experiencing anaphylaxis should be carefully instructed in regard to the circumstances under which epinephrine should be used.

### **(2) Information for Patients**

Complete patient information, including dosage, direction for proper administration and precautions can be found inside each EpiPen/EpiPen Jr Auto-Injector carton.

Epinephrine may produce symptoms and signs that include an increase in heart rate, the sensation of a more forceful heartbeat, palpitations, sweating, nausea and vomiting, difficulty breathing, pallor, dizziness, weakness or shakiness, headache, apprehension, nervousness, or anxiety. These symptoms and signs usually subside rapidly, especially with rest, quiet and recumbency. Patients with hypertension or hyperthyroidism may develop more severe or persistent effects, and patients with coronary artery disease could experience angina. Patients with diabetes may develop increased blood glucose levels

following epinephrine administration. Patients with Parkinson's disease may notice a temporary worsening of symptoms.

In case of accidental injection, the patient should be advised to immediately go to the emergency room for treatment. Since the epinephrine in the EpiPen Auto-Injector is a strong vasoconstrictor when injected into the digits, hands or feet, treatment should be directed at vasodilation if there is such an inadvertent administration to these areas (see **ADVERSE REACTIONS**).

The carrier tube is not waterproof.

The blue safety release helps prevent accidental injection and should be kept on until it will be used.

### **(3) Drug Interactions**

Patients who receive epinephrine while concomitantly taking cardiac glycosides or diuretics should be observed carefully for the development of cardiac arrhythmias.

The effects of epinephrine may be potentiated by tricyclic antidepressants, monoamine oxidase inhibitors, levothyroxine sodium, and certain antihistamines, notably chlorpheniramine, tripeleminamine and diphenhydramine.

The cardiostimulating and bronchodilating effects of epinephrine are antagonized by beta-adrenergic blocking drugs, such as propranolol. The vasoconstricting and hypertensive effects of epinephrine are antagonized by alpha-adrenergic blocking drugs, such as phentolamine. Ergot alkaloids may also reverse the pressor effects of epinephrine.

### **(4) Carcinogenesis, Mutagenesis, Impairment of Fertility**

Epinephrine and other catecholamines have been shown to have mutagenic potential *in vitro* and to be an oxidative mutagen in a WP2 bacterial reverse mutation assay. Epinephrine had a moderate degree of mutagenicity, and was positive in the DNA Repair test with *B. subtilis* (REC) assay, but was not mutagenic in the *Salmonella* bacterial reverse mutation assay.

Studies of epinephrine after repeated exposure in animals to evaluate the carcinogenic and mutagenic potential or the effect on fertility have not been conducted. This should not prevent the use of epinephrine under the conditions noted under **INDICATIONS AND USAGE**.

### **(5) Usage in Pregnancy**

Pregnancy Category C: There is no study on the acute effect of epinephrine on pregnancy. Epinephrine has been shown to have developmental effects when administered subcutaneously in rabbits at a dose of 1.2 mg/kg daily for two to three days (approximately 30 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m<sup>2</sup> basis), in mice at a subcutaneous dose of 1 mg/kg daily for 10 days (approximately 7 times the maximum daily subcutaneous or intramuscular dose on a mg/m<sup>2</sup> basis) and in hamsters at a subcutaneous dose of 0.5 mg/kg daily for 4 days (approximately 5 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m<sup>2</sup> basis). These effects were not seen in mice at a subcutaneous dose of 0.5 mg/kg daily for 10 days (approximately 3 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m<sup>2</sup> basis). Although, there are no adequate and well-controlled studies in pregnant women, epinephrine should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known if epinephrine passes into breast milk.

## **ADVERSE REACTIONS**

Adverse reactions to epinephrine include transient, moderate anxiety; apprehensiveness; restlessness; tremor; weakness; dizziness; sweating; palpitations; pallor; nausea and vomiting; headache; and/or respiratory difficulties. These symptoms occur in some persons receiving therapeutic doses of epinephrine, but are more likely to occur in patients with hypertension or hyperthyroidism. Arrhythmias,

including fatal ventricular fibrillation, have been reported in patients with underlying cardiac disease or certain drugs (see **PRECAUTIONS, Drug Interactions**). Rapid rises in blood pressure have produced cerebral hemorrhage, particularly in elderly patients with cardiovascular disease. Angina may occur in patients with coronary artery disease. The potential for epinephrine to produce these types of adverse reactions does not contraindicate its use in an acute life-threatening allergic reaction.

Accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area (see **WARNINGS**). Adverse events experienced as a result of accidental injections may include increased heart rate, local reactions including injection site pallor, coldness and hypoaesthesia or injury at the injection site resulting in bruising, bleeding, discoloration, erythema or skeletal injury.

## **OVERDOSAGE**

Epinephrine is rapidly inactivated in the body and treatment following overdose with epinephrine is primarily supportive. If necessary, pressor effects may be counteracted by rapidly acting vasodilators or alpha-adrenergic blocking drugs. If prolonged hypotension follows such measures, it may be necessary to administer another pressor drug.

Overdosage of epinephrine may produce extremely elevated arterial pressure, which may result in cerebrovascular hemorrhage, particularly in elderly patients.

Overdosage may also result in pulmonary edema because of peripheral vascular constriction together with cardiac stimulation. Treatment consists of a rapidly acting alpha-adrenergic blocking drug and/or respiratory support.

Epinephrine overdosage can also cause transient bradycardia followed by tachycardia and these may be accompanied by potentially fatal cardiac arrhythmias. Premature ventricular contractions may appear within one minute after injection and may be followed by multifocal ventricular tachycardia (prefibrillation rhythm). Subsidence of the ventricular effects may be followed by atrial tachycardia and occasionally by atrioventricular block. Treatment of arrhythmias consists of administration of a beta-blocking drug such as propranolol.

Overdosage sometimes results in extreme pallor and coldness of the skin, metabolic acidosis and kidney failure. Suitable corrective measures must be taken in such situations.

## **DOSAGE AND ADMINISTRATION**

EpiPen or EpiPen Jr Auto-Injector prescribers should ensure that the patient or caregiver understands the indications and use of this product. A health care provider should review the patient instructions and operation of the EpiPen or EpiPen Jr Auto-Injector, in detail, with the patient or caregiver. Inject EpiPen or EpiPen Jr intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. See detailed Directions for Use on the accompanying Patient Instructions.

Selection of the appropriate dosage strength is determined according to patient body weight.

EpiPen Auto-Injector delivers 0.3 mg epinephrine injection (0.3 mL, 1:1000) and is intended for patients who weigh 30 kg or more (approximately 66 pounds or more).

EpiPen Jr Auto-Injector delivers 0.15 mg epinephrine injection (0.3 mL, 1:2000) and is intended for patients who weigh 15 to 30 kg (33 – 66 pounds).

Each EpiPen or EpiPen Jr Auto-Injector contains a single dose of epinephrine. Since the doses of epinephrine delivered from EpiPen or EpiPen Jr Auto-Injector are fixed, consider using other forms of injectable epinephrine if doses lower than 0.15 mg are deemed necessary. The prescriber should carefully assess each patient to determine the most appropriate dose of epinephrine, recognizing the life-threatening nature of the reactions for which this drug is indicated. With severe persistent anaphylaxis, repeat injections with an additional EpiPen Auto-Injector may be necessary.

Patients should be instructed to periodically visually inspect the epinephrine solution for particulate matter and discoloration. If the solution contains particulate matter or develops a pinkish or brown color, the patient should immediately contact their physician for a replacement, since these changes indicate that the effectiveness of the drug product may be decreased.

## HOW SUPPLIED

EpiPen Auto-Injectors (epinephrine injections, USP, 1:1000, 0.3 mL) are available in individual cartons, NDC 49502-500-01, and as EpiPen 2-Pak<sup>®</sup>, NDC 49502-500-02, a pack that contains two EpiPen Auto-Injectors (epinephrine injections, USP, 1:1000, 0.3 mL) and one EpiPen Auto-Injector trainer device.

EpiPen Jr Auto-Injectors (epinephrine injection, USP, 1:2000, 0.3 mL) are available in individual cartons, NDC 49502-501-01, and as EpiPen Jr 2-Pak<sup>®</sup>, NDC 49502-501-02, a pack that contains two EpiPen Jr Auto-Injectors (epinephrine injections, USP, 1:2000, 0.3 mL) and one EpiPen Auto-Injector trainer device.

EpiPen 2-Pak<sup>®</sup> and EpiPen Jr 2-Pak<sup>®</sup> also includes an S-clip to clip two cases together.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15°C-30°C (59°F-86°F) (See USP Controlled Room Temperature). Do not refrigerate. Protect from light. Contains no latex.

Rx only.

MANUFACTURED FOR Mylan Specialty L.P.,  
Basking Ridge, NJ 07920, USA  
by Meridian Medical Technologies, Inc.,  
Columbia, MD 21046, USA, a Pfizer company

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## PATIENT INFORMATION

### EPIPEN<sup>®</sup>

**(epinephrine) Auto-Injector 0.3 mg**

**EpiPen<sup>®</sup> = one dose of 0.30 mg epinephrine (USP, 1:1000, 0.3 mL)**

### EPIPEN JR<sup>®</sup>

**(epinephrine) Auto-Injector 0.15 mg**

**EpiPen Jr<sup>®</sup> = one dose of 0.15 mg epinephrine (USP, 1:2000, 0.3 mL)**

### For allergic emergencies (anaphylaxis)

Read this Patient Information Leaflet carefully before using the EpiPen<sup>®</sup> Auto-Injector or EpiPen Jr<sup>®</sup> Auto-Injector (henceforth referred to as EpiPen or EpiPen Jr Auto-Injector), and each time you get a refill. There may be new information. You should know how to use the EpiPen or EpiPen Jr Auto-Injector before you have an allergic emergency.

This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

### What is the most important information I should know about the EpiPen and EpiPen Jr Auto-Injector?

1. **EpiPen and EpiPen Jr Auto-Injectors contain epinephrine, a medicine used to treat allergic emergencies (anaphylaxis).**

Anaphylaxis can be life threatening, can happen within minutes, and can be caused by stinging and biting insects, allergy injections, foods, medicines, exercise, or unknown causes. Symptoms of

anaphylaxis may include:

- trouble breathing
  - wheezing
  - hoarseness (changes in the way your voice sounds)
  - hives (raised reddened rash that may itch)
  - severe itching
  - swelling of your face, lips, mouth, or tongue
  - skin rash, redness, or swelling
  - fast heartbeat
  - weak pulse
  - feeling very anxious
  - confusion
  - stomach pain
  - losing control of urine or bowel movements (incontinence)
  - dizziness, fainting, or “passing out” (unconsciousness)
2. **Always carry your EpiPen or EpiPen Jr Auto-Injector with you because you may not know when anaphylaxis may happen.**
- Talk to your healthcare provider if you need additional units to keep at work, school, or other locations. Tell your family members and others where you keep your EpiPen or EpiPen Jr Auto-Injector and how to use it before you need it. You may be unable to speak in an allergic emergency.
3. **When you have an allergic emergency (anaphylaxis) use the EpiPen or EpiPen Jr Auto-Injector right away. Get emergency medical help right away.**
- You may need further medical attention. You may need a second EpiPen or EpiPen Jr Auto-Injector should symptoms persist or recur. More than two sequential doses of epinephrine for a single episode should only be administered by a healthcare provider.

### **What are the EpiPen and EpiPen Jr Auto-Injectors?**

- EpiPen and EpiPen Jr Auto-Injector are disposable, prefilled automatic injection devices used to treat life-threatening, allergic emergencies including anaphylaxis in people who are at risk for or have a history of serious allergic emergencies. They contain a single dose of epinephrine.
- EpiPen and EpiPen Jr Auto-Injector are for immediate self (or caregiver) administration and do not take the place of emergency medical care. You should get emergency help right away after using the EpiPen and EpiPen Jr Auto Injector.
- EpiPen and EpiPen Jr Auto-Injector are for people who have been prescribed this medication by their healthcare provider.
- The EpiPen Auto-Injector (0.3 mg) is for patients who weigh 66 pounds or more (30 kilograms or more).
- The EpiPen Jr Auto-Injector (0.15 mg) is for patients who weigh about 33 to 66 pounds (15 to 30 kilograms).
- It is not known if EpiPen and EpiPen Jr Auto-Injectors are safe and effective in children who weigh less than 33 pounds (15 kilograms).

### **What should I tell my healthcare provider before using the EpiPen or EpiPen Jr Auto-Injector?**

**Before you use EpiPen or EpiPen Jr Auto-Injector, tell your healthcare provider about all your medical conditions, but especially if you:**

- have heart problems or high blood pressure
- have diabetes
- have thyroid conditions
- have asthma
- have a history of depression
- have Parkinson's disease

- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if epinephrine will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if epinephrine passes into your breast milk.

**Tell your healthcare provider about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements. Inform your healthcare provider of all known allergies.

Especially tell your healthcare provider if you take certain asthma medications.

EpiPen or EpiPen Jr Auto-Injector and other medicines may affect each other, causing side effects. EpiPen or EpiPen Jr Auto-Injector may affect the way other medicines work, and other medicines may affect how the EpiPen or EpiPen Jr Auto-Injector works.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

Use your EpiPen or EpiPen Jr Auto-Injector for treatment of anaphylaxis as prescribed by your healthcare provider, regardless of medical conditions or medication.

### **How should I use the EpiPen and EpiPen Jr Auto-Injector?**

- Each EpiPen or EpiPen Jr Auto-Injector contains only 1 dose of medicine.
- The EpiPen or EpiPen Jr Auto-Injector should be injected into the muscle of your outer thigh. It can be injected through your clothing if needed.
- Read the Instructions for Use at the end of this Patient Information Leaflet about the right way to use EpiPen and EpiPen Jr Auto-Injector.
- Use your EpiPen or EpiPen Jr Auto-Injector exactly as your healthcare provider tells you to use it.
- **Caution: Never put your thumb, fingers, or hand over the orange tip. Never press or push the orange tip with your thumb, fingers, or hand.**

The needle comes out of the orange tip. Accidental injection into finger, hands or feet may cause a loss of blood flow to these areas. **If this occurs, go immediately to the nearest emergency room.** Tell the healthcare provider where on your body you received the accidental injection.

- Your EpiPen and EpiPen Jr Auto-Injector may come packaged with an EpiPen Auto-Injector Trainer and separate Trainer Instructions for Use. **The EpiPen Auto-Injector Trainer has a grey color. The grey EpiPen Auto-Injector Trainer contains no medicine and no needle.** Practice with your EpiPen Auto-Injector Trainer before an allergic emergency happens to make sure you are able to safely use the real EpiPen and EpiPen Jr Auto-Injector in an emergency. Always carry your real EpiPen or EpiPen Jr Auto-Injector with you in case of an allergic emergency. Additional training resources are available at [www.epipen.com](http://www.epipen.com).
- Do not drop the carrier tube or auto-injector. If the carrier tube or auto-injector is dropped, check for damage and leakage. Discard the auto-injector and carrier tube, and replace if damage or leakage is noticed or suspected.

### **What are the possible side effects of the EpiPen and EpiPen Jr Auto-Injector?**

**EpiPen and EpiPen Jr Auto-Injector may cause serious side effects.**

The EpiPen or EpiPen Jr Auto-Injector should only be injected into the middle of your outer thigh (upper leg). Do not inject the EpiPen or EpiPen Jr Auto-Injector into your:

- vein
- buttock
- fingers, toes, hands, or feet

If you accidentally inject EpiPen or EpiPen Jr Auto-Injector into any other part of your body, go immediately to the nearest emergency room. Tell the healthcare provider where on your body you received the accidental injection.

**If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have longer lasting side effects when you take the EpiPen or EpiPen Jr Auto-Injector.** Talk to your healthcare provider about all your medical conditions.

Common side effects of the EpiPen and EpiPen Jr Auto-Injector include:

- fast, irregular or “pounding” heartbeat
- sweating
- headache
- weakness or shakiness
- paleness
- feelings of over excitement, nervousness or anxiety
- dizziness
- nausea and/or vomiting
- breathing problems

These side effects may go away with rest. **Tell your healthcare provider if you have any side effect that bothers you or that does not go away.**

These are not all the possible side effects of the EpiPen or EpiPen Jr Auto-Injector. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **How should I store the EpiPen and EpiPen Jr Auto-Injector?**

- Store at 68° to 77° F (20° to 25° C).
- Protect from light.
- **Do not** expose to extreme cold or heat. For example, do **not** store in your vehicle's glove box and do **not** store in the refrigerator or freezer.
- Examine contents in the clear window of your auto-injector periodically. The solution should be clear. If the solution is discolored (pinkish or brown color) or contains solid particles, replace the unit.
- Always keep your EpiPen or EpiPen Jr Auto-Injector in the carrier tube to protect it from damage; however, the carrier tube is not waterproof.
- The blue safety release helps to prevent accidental injection of the device. Keep the blue safety release on until you need to use it.
- Your EpiPen or EpiPen Jr Auto-Injector has an expiration date. Replace it before the expiration date.

#### **General information about the safe and effective use of the EpiPen and EpiPen Jr Auto-Injector:**

Do not use the EpiPen or EpiPen Jr Auto-Injector for a condition for which it was not prescribed. Do not give your EpiPen or EpiPen Jr Auto-Injector to other people.

This Patient Information Leaflet summarizes the most important information about the EpiPen and EpiPen Jr Auto-Injectors. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about the EpiPen and EpiPen Jr Auto-Injector that is written for health professionals.

For more information and video instructions on the use of the EpiPen and EpiPen Jr Auto-Injector, go to [www.epipen.com](http://www.epipen.com) or call 1-800-395-3376.

#### **What are the ingredients in EpiPen and EpiPen Jr Auto-Injector?**

**Active Ingredients:** Epinephrine

**Inactive Ingredients:** sodium chloride, sodium metabisulfite, hydrochloric acid, and water. The EpiPen and EpiPen Jr Auto-Injector contain **no latex**.

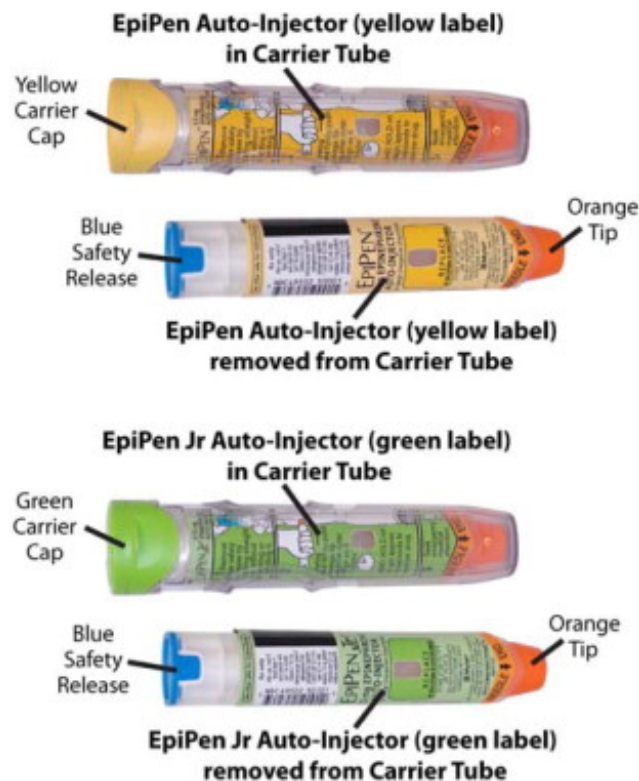
## Important Information

- The EpiPen Auto-Injector has a yellow colored label.
- The EpiPen Jr Auto-Injector has a green colored label.
- The EpiPen Trainer has a grey color, and contains no medicine and no needle.
- Your auto-injector is designed to work through clothing.
- The blue safety release on the EpiPen and EpiPen Jr Auto-Injector helps to prevent accidental injection of the device. Keep the blue safety release on until you need to use it.
- Only inject into outer thigh. Never inject into any other part of the body.
- Never put your thumb, fingers, or your hand over the orange tip. The needle comes out of the orange tip.
- If an accidental injection happens, get medical help right away.
- Do not place patient information or any other foreign objects in carrier with Auto-Injector, as this may prevent you from removing the Auto-Injector for use.

## Instructions for Use

Carefully read these Instructions for Use before you need to use your EpiPen or EpiPen Jr Auto-Injector. Before you use your EpiPen or EpiPen Jr Auto-Injector, make sure your healthcare provider shows you the right way to use it. If you have any questions, ask your healthcare provider.

### Your EpiPen and EpiPen Jr Auto-Injector



### 3-Step Easy To Follow Instructions:

1. **Prepare** the EpiPen or EpiPen Jr Auto-Injector For Injection
2. **Administer** the EpiPen or EpiPen Jr Auto-Injector
3. **Finalize** the Injection Process (See detailed instructions below)

1. **Prepare** the EpiPen or EpiPen Jr Auto-Injector For Injection

**Remove the auto-injector from the clear carrier tube.**

Flip open the yellow cap of your EpiPen or the green cap of your EpiPen Jr Auto-Injector carrier

tube.



Tip and slide the auto-injector out of the carrier tube.



**Grasp the auto-injector in your fist with the orange tip pointing downward.**

With your other hand, **remove the blue safety release by pulling straight up without bending or twisting it.**



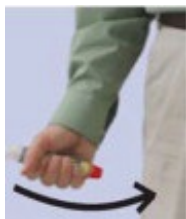
**Note:**

- The needle comes out of the orange tip.
- Never put your thumb, fingers or hand over the orange tip.

2. **Administer** the EpiPen or EpiPen Jr Auto-Injector

Hold the auto-injector with orange tip near the outer thigh.

**Swing and firmly push the orange tip against the outer thigh** until it 'clicks'. Keep the auto-injector firmly pushed against the thigh at a 90° angle (perpendicular) to the thigh.



**Hold firmly against the thigh for approximately 10 seconds to deliver the drug. The injection is now complete.**

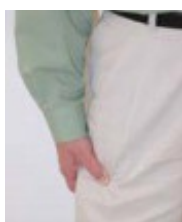


### 3. **Finalize** the Injection Process

Remove the auto-injector from the thigh. The orange tip will extend to cover the needle.



Massage the injection area for 10 seconds.



**Get emergency medical help right away.** You may need further medical attention. You may need a second EpiPen or EpiPen Jr Auto-Injector should symptoms persist or recur.

#### Note:

- Take your used auto-injector with you when you go to see the healthcare provider.
- Tell the healthcare provider that you have received an injection of epinephrine. Show the healthcare provider where you received the injection.
- Give your used EpiPen or EpiPen Jr Auto-Injector to a healthcare provider for inspection and proper disposal.
- Ask for a refill, if needed.
- The used auto-injector with extended needle cover will not fit in the carrier tube.
- Most of the liquid medicine stays in the auto-injector and cannot be reused. You have received the correct dose of the medicine if the orange needle tip is extended and the window is blocked.
- Your EpiPen and EpiPen Jr Auto-Injector may come packaged with an EpiPen Auto-Injector Trainer and separate Trainer Instructions for Use. **The EpiPen Trainer has a grey color. The grey EpiPen Trainer contains no medicine and no needle. Practice with your EpiPen Trainer, but always carry your real EpiPen or EpiPen Jr Auto-Injector in case of an allergic emergency.**
- Do not attempt to take the EpiPen or EpiPen Jr Auto-Injector apart.

This Patient Information and Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured for:

Mylan Specialty L.P., Basking Ridge, NJ 07920, USA  
by Meridian Medical Technologies, Inc.,

Columbia, MD 21046, USA, a Pfizer company

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L.P. of Basking Ridge, NJ 07920, USA

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8/2012 03-855-03 0001726



**MyEpiPen.com**

Register your EpiPen or EpiPen Jr Auto-Injector at **MyEpiPen.com** and find out more about:

- Free EpiPen Auto-Injector **Refill Reminder Program**. It is important to keep your auto-injector up-to-date.  
Register up to 6 EpiPen or EpiPen Jr Auto-Injectors and receive automatic **Refill Reminder Alerts**.
- Receive periodic information related to allergies and allergens.
- Instructional Video

For more information about EpiPen or EpiPen Jr Auto-Injectors and proper use of the product, visit [www.epipen.com](http://www.epipen.com).

### **EpiPen® Trainer Instructions For Use**

**In an emergency: Do not use the grey Trainer. Use your yellow EpiPen® or green EpiPen Jr® Auto-Injector.**

#### **Important Information**

- **The Trainer label has a grey color.**
- **The Trainer contains no medicine and no needle.**
- Practice with the grey colored Trainer before an allergic emergency (anaphylaxis) happens to make sure you are able to safely use the real yellow EpiPen or green EpiPen Jr Auto-Injector in case of an emergency.
- Always carry your real EpiPen or EpiPen Jr Auto-Injector in case of an allergic emergency.

#### **Practice Instructions**

Familiarize yourself with this grey Trainer. Practice until you are comfortable using it.

#### **Your grey colored Trainer:**



- Never put your thumb, other fingers, or hand over the Orange Tip.
- The Orange Tip is where the needle comes out of your EpiPen or EpiPen Jr Auto-Injector.

### 3-Step Easy to Follow Instructions

#### 1. **Prepare** the Trainer For Simulated Injection

- Grasp the grey Trainer in your fist with the orange tip pointing downward
- With your other hand, remove blue safety release by pulling straight up without bending or twisting it
- Removing the blue safety release unlocks the Trainer



#### 2. **Administer** the Trainer Simulation

- Hold the Trainer with the orange tip near the outer thigh
- Swing and firmly push the orange tip against the outer thigh until it 'clicks.' Keep the Trainer firmly pushed against the thigh at a 90° angle (perpendicular) to the thigh. Hold firmly against the thigh for approximately 10 seconds
- Remove the Trainer from the thigh. The orange tip automatically extends out after use



#### Note:

- The actual auto-injector is made to work through clothing
- Do not inject into any other part of the body

#### 3. **To reset** the Trainer

- Put the blue safety release back on the Trainer
- Place the orange tip on a hard surface
- Squeeze the sides of the orange tip and push down on the Trainer with the other hand



**Note: With the actual yellow EpiPen or green EpiPen Jr Auto-Injector, the orange tip covers the needle after self-injection to help protect you from accidentally sticking yourself or others.**

### **Practice Session Information**

**In case of an allergic emergency, use the real yellow EpiPen or green EpiPen Jr Auto-Injector and not the grey Trainer.**

Follow instructions on the reverse side of this insert under 3-Step Easy to Follow Instructions. Repeat as often as needed until you are able to self-inject quickly and correctly.

Reread:

- These Trainer Instructions for Use
- The “Patient Information” that comes with your EpiPen or EpiPen Jr Auto-Injector

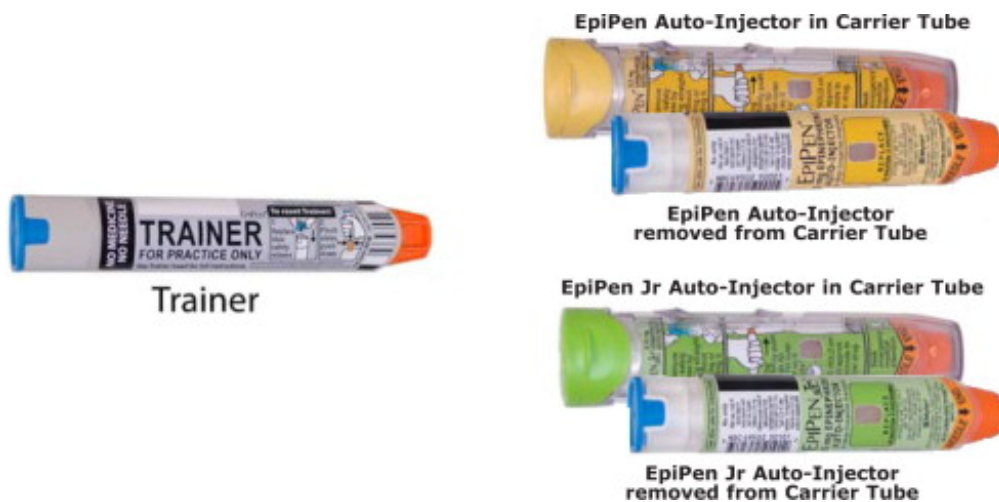
Train others who could help you in an emergency:

- Your parents, teachers, or friends should know how to help you during an allergic emergency (anaphylaxis). Before an emergency occurs, have them:
  - Practice activating the Trainer
  - Read these Trainer Instructions and the “Patient Information”

For more information about the EpiPen and EpiPen Jr Auto-Injector and the proper use of the products, go to [www.epipen.com](http://www.epipen.com).

### **Caution**

**Important differences between the Trainer and your yellow EpiPen or green EpiPen Jr Auto-Injector**



Contains medication? --- No ----- Yes

Has needle? ----- No ----- Yes

Comes in Carrier Tube?-- No ----- Yes

Color of label ----- Grey ----- Yellow (EpiPen)

Green (EpiPen Jr)

Has expiration date? ---- No ----- Yes

Can be reused? -----Yes ----- No (use only once)

Okay to remove and

Replace safety release? - Yes ----- No (remove just once before use)

Pressure needed to hold

against thigh ----- Moderate ----- Strong

This Trainer Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured for Mylan Specialty L.P., Basking Ridge, NJ 07920, USA by Meridian Medical Technologies, Inc., Columbia, MD 21046, USA, a Pfizer company

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8/2012

0001679

03-856-01

PRINCIPAL DISPLAY PANEL – EpiPen 0.3 mg AUTO-INJECTOR LABEL

**See other side for instructions**

**Rx only**

After use, most of liquid stays in auto-injector and can't be reused.

Delivers 0.3 mg intramuscular dose of epinephrine from epinephrine injection 1:1000 USP (0.3 mL).

Each 0.3 mL also contains 1.8 mg sodium chloride and 0.5 mg sodium metabisulfite.

**EPIPEN®**

**0.3 mg Epinephrine**

**Auto-Injector**

*for Allergic Emergencies (Anaphylaxis)*

**REPLACE**

**IF SOLUTION IS DISCOLORED**

**STORE AT 68°C TO 77° F (20° TO 25° C)**

**DO NOT REFRIGERATE.**

**PROTECT FROM LIGHT**

**CONTAINS NO LATEX**

**Mylan®**

Mfd. for Mylan Specialty L.P., Basking Ridge, NJ 07920, USA

by Meridian Medical Technologies, Inc.

Columbia, MD 21046 USA, a Pfizer company

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**Made in U.S.A.**

# EPIPEN<sup>®</sup> 0.3 mg EPINEPHRINE AUTO-INJECTOR

See other side for instructions

**1 Remove blue safety release by pulling straight up without bending or twisting it.**



**2**

**Swing and firmly push orange tip against outer thigh so it "clicks"**



**AND HOLD on thigh approx. 10 seconds to deliver drug.**

**3**

**Seek emergency medical attention.**



**NEEDLE ↓ END**

EpiPen<sup>®</sup> Auto-Injector utilizes Truject<sup>®</sup> technology.  
US Patent 7,449,012 • 0001610 • 03-696-04



## Rx only

After use, most of liquid stays in auto-injector and can't be reused. Delivers 0.3 mg intramuscular dose of epinephrine from epinephrine injection 1:1000 USP (0.3 mL). Each 0.3 mL also contains 1.8 mg sodium chloride and 0.5 mg sodium metabisulfite.

# EPIPEN<sup>®</sup> 0.3 mg EPINEPHRINE AUTO-INJECTOR

for Allergic Emergencies (Anaphylaxis)

**REPLACE IF SOLUTION IS DISCOLORED**

**STORE AT 68° TO 77° F (20° TO 25° C)**

**DO NOT REFRIGERATE  
PROTECT FROM LIGHT  
CONTAINS NO LATEX**

**Mylan<sup>®</sup>**

Mfd. for Mylan Specialty L.P., Basking Ridge, NJ 07920, USA  
by Meridian Medical Technologies, Inc.  
Columbia, MD 21046, USA, a Pfizer company

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Made in U.S.A.

**NEEDLE ↓ END**

**Rx only**

After use, most of liquid stays in auto-injector and can't be reused.

Delivers 0.15 mg intramuscular dose of epinephrine from epinephrine injection 1:2000 USP (0.3 mL).

Each 0.3 mL also contains 1.8 mg sodium chloride and 0.5 mg sodium metabisulfite.

**EPIPEN Jr<sup>®</sup>**

**0.15 mg Epinephrine**

**Auto-Injector**

*for Allergic Emergencies (Anaphylaxis)*

**REPLACE**

**IF SOLUTION IS DISCOLORED**

**STORE AT 68°C TO 77° F (20° TO 25° C)**

**DO NOT REFRIGERATE.**

**PROTECT FROM LIGHT**

**CONTAINS NO LATEX**

**Mylan<sup>®</sup>**

Mfd. for Mylan Specialty L.P., Basking Ridge, NJ 07920, USA

by Meridian Medical Technologies, Inc.

Columbia, MD 21046 USA, a Pfizer company

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**Made in U.S.A.**

**EPIPEN Jr<sup>®</sup>** 0.15 mg  
EPINEPHRINE  
AUTO-INJECTOR

See other side for instructions

**1** Remove  
blue safety  
release by  
pulling straight  
up without  
bending or  
twisting it.



**2**

Swing  
and firmly push  
orange tip  
against outer  
thigh so it  
"clicks"



**AND HOLD** on  
thigh approx.  
10 seconds to  
deliver drug.



**3**

Seek  
emergency  
medical  
attention. **!**



**NEEDLE ↓ END**

EpiPen Jr<sup>®</sup> Auto-Injector utilizes Truject<sup>®</sup> technology.  
US Patent 7,449,012 • 0001611 • 03-697-04



**Rx only**

After use, most of  
liquid stays in  
auto-injector and  
can't be reused.  
Delivers 0.15 mg  
intramuscular dose of  
epinephrine from  
epinephrine injection  
1:2000 USP (0.3 mL).  
Each 0.3 mL also  
contains 1.8 mg sodium  
chloride and 0.5 mg  
sodium metabisulfite.

**EPIPEN Jr<sup>®</sup>**  
**0.15 mg EPINEPHRINE  
AUTO-INJECTOR**

*for Allergic Emergencies (Anaphylaxis)*

**REPLACE  
IF SOLUTION IS DISCOLORED**

**STORE AT 68° TO 77° F  
(20° TO 25° C)**

**DO NOT REFRIGERATE  
PROTECT FROM LIGHT  
CONTAINS NO LATEX**

**Mydan<sup>®</sup>**

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Made in U.S.A.

**NEEDLE ↓ END**

NDC 49502-500-01

*Rx only*

*For Allergic Emergencies (Anaphylaxis) 0.3 mg each*

**EPIPEN® (Epinephrine) Auto-Injector 0.3 mg**

**For more information please**

**visit [www.epipen.com](http://www.epipen.com)**

**Mylan®**



PRINCIPAL DISPLAY PANEL – EpiPen Jr 0.15 mg Carton Label

NDC 49502-501-01

*Rx only*

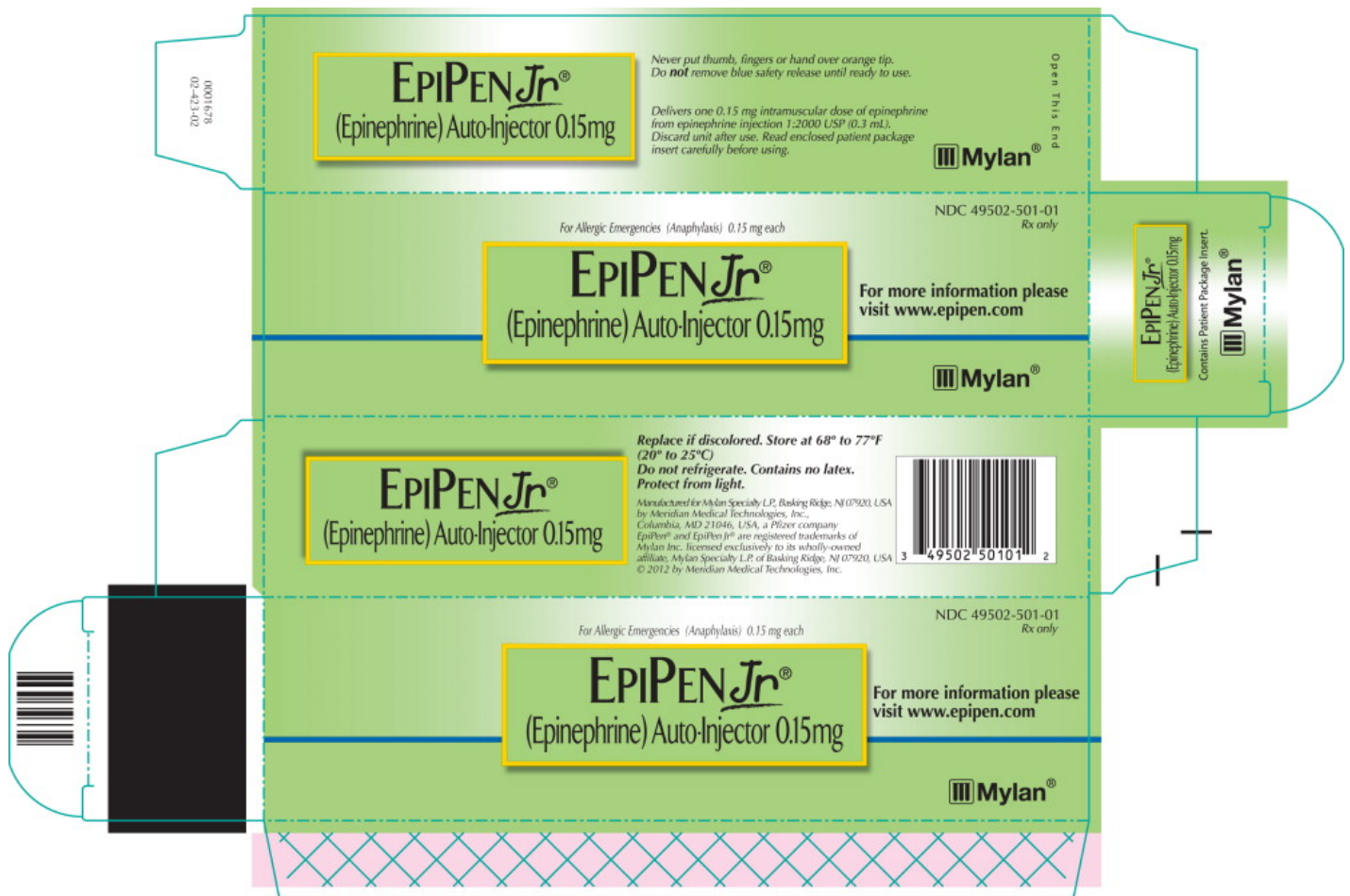
*For Allergic Emergencies (Anaphylaxis) 0.15 mg each*

**EPIPEN Jr® (Epinephrine) Auto-Injector 0.15 mg**

**For more information please**

**visit [www.epipen.com](http://www.epipen.com)**

**Mylan®**



## PRINCIPAL DISPLAY PANEL – EpiPen 2-Pak 0.3 mg Carton Label

NDC 49502-500-02

*Rx only.*

*For Allergic Emergencies (Anaphylaxis) 0.3 mg each*

**EpiPen 2-Pak®  
(Epinephrine) Auto-Injectors 0.3 mg**

Each carton contains: **Two yellow EpiPen®** Auto-Injectors  
**One grey Trainer**



PRINCIPAL DISPLAY PANEL – EpiPen Jr 2-Pak 0.15 mg Carton Label

NDC 49502-501-02

*Rx only.*

*For Allergic Emergencies (Anaphylaxis) 0.15 mg each*

**EpiPen Jr 2-Pak®**  
**(Epinephrine) Auto-Injectors 0.15 mg**

Each carton contains: **Two green EpiPen Jr® Auto-Injectors**  
**One grey Trainer**

00011676  
02-421-04

# EPIPEN<sup>Jr</sup> 2-PAK<sup>®</sup>

(Epinephrine) Auto-Injectors 0.15mg

Never put thumb, fingers or hand over orange tip.  
Do **not** remove blue safety release until ready to use.

EpiPen<sup>Jr</sup> 2-Pak<sup>®</sup> contains 2 EpiPen<sup>Jr</sup><sup>®</sup> Auto-Injectors and 1 Trainer.  
Each EpiPen<sup>Jr</sup><sup>®</sup> Auto-Injector delivers one 0.15 mg intramuscular dose of epinephrine from epinephrine injection 1:2000 USP (0.3 mL).  
Discard unit after use. The Trainer contains no medicine and no needle.  
Read enclosed patient package insert carefully before using.

NDC 49502-501-02

For Allergic Emergencies (Anaphylaxis) 0.15 mg each

Rx only.

# EPIPEN<sup>Jr</sup> 2-PAK<sup>®</sup>

(Epinephrine) Auto-Injectors 0.15mg

Each carton contains: **Two green EpiPen<sup>Jr</sup><sup>®</sup> Auto-Injectors**  
**One grey Trainer**

For more information please  
visit [www.epipen.com](http://www.epipen.com)

 Mylan<sup>®</sup>

# EPIPEN<sup>Jr</sup> 2-PAK<sup>®</sup>

(Epinephrine) Auto-Injectors 0.15mg


Replace if discolored. Store at 68° to 77°F  
(20° to 25°C)  
Do not refrigerate. Contains no latex.  
Protect from light.

Manufactured for Mylan Specialty LP, Basking Ridge, NJ 07920, USA  
by Meridian Medical Technologies, Inc.,  
Columbia, MD 21046, USA, a Pfizer company  
EpiPen<sup>®</sup> and EpiPen<sup>Jr</sup><sup>®</sup> are registered trademarks of  
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affiliate, Mylan Specialty LP, of Basking Ridge, NJ 07920, USA  
© 2012 by Meridian Medical Technologies, Inc.



# EPIPEN<sup>Jr</sup> 2-PAK<sup>®</sup>

(Epinephrine) Auto-Injectors 0.15mg

 Mylan<sup>®</sup>

Open This End

## Principal Display Panel – Front Trainer Label

**NO MEDICINE**  
**NO NEEDLE**

**TRAINER**  
**FOR PRACTICE ONLY**

1 **Pull off** blue safety release

2 Swing and **firmly push** orange tip against outer thigh so it 'clicks'.  
**HOLD on thigh for 10 seconds** to simulate drug delivery.

3 Tip extends after use



**NO MEDICINE  
NO NEEDLE**

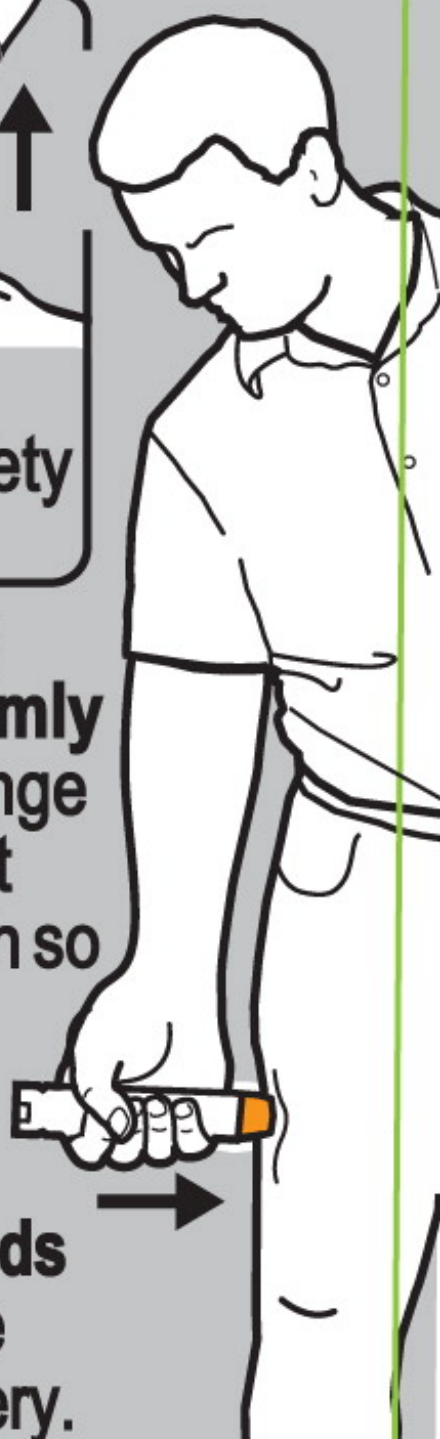
# TRAINER

FOR PRACTICE ONLY

**1**

**Pull off  
blue safety  
release**

**2** Swing  
and **firmly  
push** orange  
tip against  
outer thigh so  
it 'clicks'.  
**HOLD**  
on thigh  
**10 seconds**  
to simulate  
drug delivery.





Principal Display Panel – Back Trainer Label

**NO MEDICINE**  
**NO NEEDLE**  
**EPIPEN®**  
**TRAINER**  
**FOR PRACTICE ONLY**  
**See Trainer Insert for full instructions.**



<b>EPIPEN</b> epinephrine injection			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG LABEL	<b>Item Code (Source)</b>	NDC:49 502-500
<b>Route of Administration</b>	INTRAMUSCULAR	<b>DEA Schedule</b>	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Epinephrine (Epinephrine)	Epinephrine	0.3 mg in 0.3 mL

Inactive Ingredients	
Ingredient Name	Strength
Sodium Chloride	
Sodium Metabisulfite	
Hydrochloric Acid	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49502-500-01	1 in 1 CARTON		
1		1 in 1 CONTAINER		
1		0.3 mL in 1 SYRINGE, GLASS		
2	NDC:49502-500-02	1 in 1 CARTON		
2		1 in 1 CONTAINER		
2		0.3 mL in 1 SYRINGE, GLASS		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019430	12/22/1987	

## EPIPEN JR

epinephrine injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:49502-501
Route of Administration	INTRAMUSCULAR	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Epinephrine (Epinephrine)	Epinephrine	0.15 mg in 0.3 mL

Inactive Ingredients	
Ingredient Name	Strength
Sodium Chloride	
Sodium Metabisulfite	
Hydrochloric Acid	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49502-501-01	2 in 1 CARTON		
1		1 in 1 CONTAINER		
1		0.3 mL in 1 SYRINGE, GLASS		
2	NDC:49502-501-02	2 in 1 CARTON		
2		1 in 1 CONTAINER		
2		0.3 mL in 1 SYRINGE, GLASS		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA019430	12/22/1987		

**Labeler** - Dey Pharma L.P. (194775557)

**Registrant** - Meridian Medical Technologies, Inc. (167671341)

Establishment			
Name	Address	ID/FEI	Business Operations
Meridian Medical Technologies, Inc.		038889234	MANUFACTURE(49502-500, 49502-501), ANALYSIS(49502-500, 49502-501), STERILIZE(49502-500, 49502-501)

Establishment			
Name	Address	ID/FEI	Business Operations
Meridian Medical Technologies, Inc.		167671341	MANUFACTURE(49502-500, 49502-501), LABEL(49502-500, 49502-501), PACK(49502-500, 49502-501)

Revised: 8/2012

Dey Pharma L.P.